

REMARKS

The pending Office Action addresses and rejects claims 1, 3, 4 and 6-33.

Amendments to the Claims

Claim 22 is amended to recite that the flexible membrane extends across an opening formed in the sidewall of the catheter and that it is adapted to respond to intra-ventricular pressure changes when disposed flush across the opening. Support for the amendment can be found, for example, in paragraph 27 of the specification. Claim 29 is amended to recite that the second lumen is a permanently sealed lumen. Support for the amendment can be found, for example, in paragraph 22 of the specification. Claims 6 and 16 are canceled. No new matter is added.

Claim Objections

Claims 6 and 16 are objected to for various informalities. As noted above, claims 6 and 16 are canceled, thus obviating the basis for these rejections.

Rejections Pursuant to 35 U.S.C. §103

(1) Claims 1, 3, 4, 6, 8-10, 15, 17, 18, 21-24, and 28-29

Claims 1, 3, 4, 6, 8-10, 15, 17, 18, 21-24, and 28-29 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,951,497 of Wallace et al. in view of U.S. Patent No. 4,928,693 of Goodin. The Examiner argues that Wallace discloses the pressure sensor device substantially as claimed. The Examiner admits, however, that Wallace fails to teach a second lumen filled with an incompressible fluid, but argues that it would have been obvious it add this feature as disclosed in Goodin because it is "an equally effective means to transmit the pressure and thus provide accurate pressure readings." Applicants respectfully disagree.

Independent Claim 1

The device disclosed in Wallace is specifically designed for use with air to measure pressure inside the uterus. Wallace discloses a device for taking pressure measurements in the uterus, and includes a balloon 342 and a lumen 330 that would be inserted into the uterus with the device. The balloon and the lumen are deflated during insertion of the device due to the change in pressure. These components would then be charged with air to a known pressure. Any subsequent change in pressure in the uterus would be translated down the balloon 342 and the lumen 330 to a pressure sensor. This charging of the balloon 342 and the lumen 330 to a known and controlled pressure allows for an accurate pressure reading (See Wallace, Col. 10, lines 30-36, and Col. 13, lines 48-62). Accordingly, since Wallace's device is specifically configured for use with air, there is no motivation to modify the device of Wallace.

Not only is there no motivation to modify the device of Wallace, Wallace actually teaches away from the combination argued by the Examiner. The Federal Circuit has made it clear that references cannot be combined where references teach away from the combination. *See, e.g., In re Grasselli*, 713 F.2d 731, 743 9Fed. Cir. 1983) (holding that it is improper to combine references where the references teach away from their combination); *see also* M.P.E.P. 2145(X)(D). In Col. 11, lines 11-38, Wallace discusses the problem of fluid in the form of condensation in the air column, stating that:

The air column formed in the inner tube 30 and balloon 42 may have an amount of condensation associated therewith as a result of ambient humidity or minute amounts of water permeating through the balloon 42 or through the inner tube 30 after the IUP catheter 10 has been positioned in the uterus (which averages a temperature of about 37.degree. C.) for a period of time. To avoid an accumulation of condensation in the air column, therefore, the inner tube 30 may be structured with a moisture-collecting element 56 to draw or collect moisture within the tube 30. As shown in FIG. 3, the moisture-collecting element 56 may suitably be a line or strand 58 of hygroscopic material, such as nylon, which collects condensate and wicks and distributes the moisture along the length of the line 58. The absorbent line 58 may preferably extend from the distal end 46 of the inner tube 30 to near the proximal end 28 of the hollow outer tube 16. The line may be, for example, approximately 0.01 inch (10 mil) in diameter and is anchored to the interior wall of inner tube 30 by application of a drop of adhesive applied at the distal end of the tube, the line material drawing the adhesive along the line into the tube. The other

end of line 58 is free, but the line is rigid enough to maintain itself in place with one anchor point. The absorbent line 58 also provides a degree of structural support against collapse to the inner tube 30, which helps prevent the otherwise flexible inner tube 30 from kinking and compromising the air column, and prevents total closure of inner tube 30 upon kinking.

Thus, Wallace specifically addresses the problem of a having fluid present in the air column. To overcome this issue, the air column disclosed in Wallace is specifically designed to provide methods to remove condensation. Accordingly, Wallace teaches away from the modification suggested by the Examiner.

In addition, liquid as a method of measuring pressure was clearly known at the time of the invention of the Wallace device. However, Wallace specifically selected air for use with its device, likely because air allows for inflation of the lumen and the balloon through charging of the air column, as previously discussed.

Claim 1, and claims 4, 6, 9-10, and 21 which depend therefrom, therefore distinguish over Wallace and Goodin and represents allowable subject matter.

Independent Claim 22

In addition to the argument presented above with respect to claim 1, amended claim 22 requires that the flexible membrane extends across an opening formed in the sidewall of the catheter and that it is adapted to respond to intra-ventricular pressure changes when disposed flush across the opening. To establish a prima facie case of obviousness, the prior art reference must teach or suggest all the claim limitations. Wallace does not teach a flexible membrane that is flush across an opening in a catheter, much less during pressure changes. In FIG. 16, Wallace teaches a lumen (330) having a balloon (342) placed on the exterior of a catheter. The balloon is disposed over a distal portion of the catheter, which contains an opening. However, the balloon does not extend *across* the opening. Moreover, the balloon can only response to pressure changes when the balloon (342) is filled with air. Thus, the balloon (342) cannot remain flush with the catheter as it responds to pressure in the uterus. Accordingly, Wallace simply fails to disclose all the elements of claim 22. Goodin does not remedy this deficiency of Wallace

as Goodin fails to teach a flexible membrane extending across an opening formed in a catheter, much less a flexible membrane that remains flush with the catheter as it responds to pressure changes.

Claim 22, and claims 23, 24, and 28 which depend therefrom, therefore distinguish over Wallace and Goodin and represents allowable subject matter.

Independent Claim 29

In addition to the argument presented above with respect to claim 1, amended claim 29 requires that the second lumen is a *permanently* sealed lumen. As stated above, the prior art reference must teach or suggest all the claim limitations to establish a prima facie case of obviousness, and Wallace does not teach a second lumen that is *permanently* sealed. The lumen (330) of Wallace is inserted into the uterus with the balloon in a deflated configuration. In order to take pressure measurements, the lumen (330) is charged with air to inflate the balloon to a known pressure. Thus, the lumen is not sealed, much less permanently sealed. In fact, Wallace specifically states that the lumen can be recharged as many times as necessary (See Col. 13, lines 23-47, and Col. 14, lines 17-21 of Wallace). Accordingly, the lumen (330) cannot be *permanently* sealed.

Applicant further notes that it would not have been obvious to modify Wallace to permanently seal the lumen (330) because such a modification would change the principle operation of Wallace. As explained in §2143.01(VI) of the *MPEP*, “[i]f the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” As stated above, the device of Wallace is specifically designed to allow recharging of the air column in the event that the pressure inside the air column falls, for example, due to air dissipating through the balloon. Since a permanent seal of the lumen (330) would prevent recharging of the air column if the pressure therein falls below a normative value and would cause inaccurate pressure readings, this modification would thus change the principle operation of Wallace, and therefore would not have been obvious.

Claim 29, and claim 30 which depends therefrom, therefore distinguish over Wallace and Goodin and represents allowable subject matter.

(2) Claims 7, 11-14, 16, 20, 25-27, 31-33

Claims 7, 11-14, 16, 20, 25-27, and 31-33 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Wallace and Goodin in view of various references set forth in the Office Action. The Examiner relies on these references to teach various features recited in the dependent claims and not taught by Wallace and Goodin. As indicated above, the combination of Wallace and Goodin is not obvious. The various secondary references cited by the Examiner do not remedy the deficiencies of Wallace and Goodin. Accordingly, claims 7, 11-14, 16, 20, 25-27, and 31-33 distinguish over Wallace, Goodin, and the various secondary references and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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